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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,850	10/17/2003	David W. Burke	7404-558	9581

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1795	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)	
Office Action Summary	10/687,850	BURKE ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/15/2007 (RCE)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/15/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of October 15, 2007 does not render the application allowable.

Response to Arguments

2. Applicant's arguments filed October 15, 2007 have been fully considered but they are not persuasive.

35 U.S.C. § 103 rejections of claims 1-6 and 16

Applicant asserts that Neel as modified by Beaty teaches away from applying a signal having an AC component to a pair of dose sufficiency electrodes. In particular, Applicant argues (1) that Neel uses a pair of dose sufficiency electrodes separate from the measurement electrodes so as not to disturb the stoichiometry of the measurement zone until the measurement sequence is ready to begin, and (2) that Beaty "...teaches that the adequacy of the sample volume can be determined by applying an AC signal of

proper level directly to the measurement electrodes, without the need for separate sufficiency electrodes." So, in Applicant's view, in light of Beaty a separate pair of dose sufficiency electrodes would not be needed in Neel. The Examiner respectfully disagrees. Neel does not just provide a separate pair of dose sufficiency electrodes so as not to disturb the stoichiometry of the measurement zone until the measurement sequence is ready to begin:

> However they are arranged relative to each other, it is preferable for fill-detect electrodes **28** and **30** to be located on the distal side of reagent layer **90**. In this way, as the sample flows through sample chamber **88** toward distal end **70**, the sample will have traversed reagent layer **90** by the time it reaches fill-detect electrodes **28** and **30**. This arrangement beneficially allows the fill-detect electrodes **28** and **30** to detect not only whether sufficient blood sample is present in sample chamber **88** but also to detect whether the blood sample has become sufficiently mixed with the chemical constituents of reagent layer **90**. Thus, if reagent layer **90** covers working electrode **22**, as is preferable, then it is preferable to locate fill-detect electrodes **28** and **30** on the distal side of working electrode **22**, as in the configuration shown in FIGS. **1–3**. Other configurations may be used, however.

See column 08, lines 17-33, emphasis added.

Thus, even if an AC signal as taught by Beaty does indicate whether sample volume is adequate, as taught by Neel using a separate pair of dose sufficiency electrodes provides the additional benefits of ensuring that sample has covered the reagent layer and the measurement pair of electrodes (see Figure 3), and that the sample has sufficiently mixed with the reagent. In other words, the separate dose sufficiency electrodes ensures not only that there is enough sample, but that the sample

has spread and contacted the regions of the chamber necessary for accurate measurement.

Moreover, although Beaty does not provide a second pair of electrodes separate from the measurement electrodes on the test strip, it is noteworthy, as seen in Figure 2 of Beaty, that there are two pairs of electrical contacts (34-1, 34-2, 34-3, and the unlabeled contact opposite contact 34-2) that contact the test strip electrodes. Electrical contacts 34-2 and 34-3 are used to provide an AC signal for determining whether sufficient sample is present (col. 10: 10-25). So Beaty provides at least one additional electrical contact just for determining sample sufficiency.

Also, as seen in Figure 2 of Beaty the two electrodes on the test strip are parallel to the long sides of the test strip, run the full length of the sample chamber, and are at the side edges of the sample chamber. This is In contrast to the measurement electrodes in Neel that are essentially perpendicular to the long sides of the test strip, do not run the full length of the test strip, and extend the full width of the sample chamber. So it is not clearly apparent that removing the sample sufficiency electrodes 28 and 30 of Neel would be redundant as Applicant alleges if the sample sufficiency AC signal of Beaty is just applied to the measurement electrodes 22 and 24 of Neel.

In conclusion, for the reasons discussed above the Examiner does not agree that if an AC signal is used as taught by Beaty in the invention of Neel that a separate pair of dose sufficiency electrodes would not be necessary.

Status of the Rejections pending since the Office action of July 17, 2007

3. All previous rejections are withdrawn.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-5 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. US 6,743,635 B2 ("Neel") in view of Beaty et al. (US 6,645,368 B1) ("Beaty").

Addressing claim 1, Neel discloses a method of performing a measurement on a biological fluid in a test strip (abstract) comprising

providing a biological fluid test strip (10) including

a capillary fill chamber (66) extending a length along the test strip from an intake opening (68) to a terminus (70)(Figures 1-3),

a first pair of electrodes (22,24) in operative communication with the chamber (Figure 2),

and

a second pair of electrodes (28,30) in operative communication with the chamber (Figure 2);

dosing the test strip with a biological fluid effective to cause the biological fluid to flow from the intake opening toward the terminus (col. 14:43-51);

applying a first test signal to at least one of the first pair of electrodes (col. 14:48-55);

measuring a first response to the first test signal (col. 14:48-55);

maintaining the first pair of electrodes in an inoperative state after the measuring the first response (col. 14:55-57);

applying a second test signal to at least one of the second pair of electrodes

(col. 14:67 – col. 15:03);

measuring a second response to the second test signal (col. 14:67 – col. 15:03); and

performing a measurement upon the biological fluid after the measuring the second response (col. 15:26-28).

The second test signal applied by Neel appears to be just a DC test signal (col. 14:67 – col. 15:03).

Beaty discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip for determining the concentration of a medically significant component of a biological fluid. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel as the second test signal because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit, glucose (or other

analyte) concentration, temperature, bilirubin concentration, uric acid concentration, and oxygen concentration. See 06:20-42.

Addressing claim 2, Neel et al discloses the measuring of the first response to the first test signal is indicative of contact between the first pair of electrodes and the biological fluid (Column 14, lines 48-51).

Addressing claim 3, Neel et al discloses measuring the first response to the first test signal to indicate contact of the first pair of electrodes and the fluid (Column 14, line 63 through Column 15, line 11).

Addressing claim 4, Neel et al discloses measuring the second response to the second test signal to indicate contact of the second pair of electrodes and the fluid (Column 14, lines 48-55).

Addressing claim 5, Neel et al discloses performing a measurement on the biological fluid by applying a test signal to at least one of the first pair of electrodes (Column 15, lines 47-58).

Addressing claim 16, for the additional limitation of this claim note that Beaty teaches that the second test signal may be a pure AC signal or may have a DC offset. See col. 06:20-57 and col. 11:32-36.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. US 6,743,635 B2 ("Neel") in view of Beaty et al. US 6,645,368 B1 ("Beaty") as applied to claims 1-5 and 16 above, and further in view of Feldman et al. US 6,592,745 B1 ("Feldman").

Neel does not mention providing a third pair of electrodes in operative communication with the chamber wherein the performing a measurement upon the

biological fluid includes applying a measurement test signal to at least one of the third pair of electrodes.

Feldman discloses an electrochemical biosensor for performing a measurement on a biological fluid. The biosensor comprises multiple working electrodes (42, 44, 46), along with counter electrodes, to form electrode pairs that are in operative communication with a sample chamber (26) on a base material (48) (col. 49:7-12). It would have been obvious to provide at least one additional pair of electrodes, to form a third electrode pair, as taught by Feldman in the invention of Neel as modified by Beaty because as taught by Feldman, "... multiple electrode sensors may be used to test a variety of analytes using a single sample ..." and "[m]ultiple electrode sensors may also be used to improve the precision of the resulting readings ...". See col. 48:16-59.

7. Claims 7-15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. US 6,743,635 B2 ("Neel") in view of Feldman et al. US 6,592,745 B1 ("Feldman").

Addressing claim 7, Neel discloses a method of indicating acceptable fill time of a biological fluid in a test strip comprising:

providing a biological fluid test strip (10) including

a capillary fill chamber (66) extending a length along the test strip from an intake

opening (68) to a terminus (70) (Figures 1-3),

a first pair of electrodes (22,24) in operative communication with the chamber (Figure 2),

a second pair of electrodes (28, 30) in operative communication with the chamber (Figure 2); and

dosing the test strip with a biological fluid effective to cause the biological fluid to flow from the intake opening toward the terminus (col. 14:43-51);

flowing a biological fluid from the opening toward the terminus (col. 14:43-51);

first determining when the biological fluid contacts the first electrodes (col. 14:35-60, step 348 in Figure 17);

second determining when the biological fluid contacts the second electrodes (col. 14:63 – col. 15:11);

determining a fill time value based upon the first determining and the second determining (col. 14:27 – col. 15:11 and steps 348-358 in flowchart in Figure 17); and

comparing the fill time value to a predetermined value (col. 05:02-11).

Neel does not mention providing a third pair of electrodes in operative communication with the chamber and measuring an analyte concentration of the biological fluid using the third electrodes.

Feldman discloses an electrochemical biosensor for performing a measurement on a biological fluid. The biosensor comprises multiple working electrodes (42, 44, 46), along with counter electrodes, to form electrode pairs that are in operative communication with a sample chamber (26) on a base material (48) (col. 49:7-12). It would have been obvious to provide at least one additional pair of electrodes, to form a third electrode pair, as taught by Feldman in the invention of Neel as modified by Beaty because as taught by Feldman, "... multiple electrode sensors may be used to test a variety of analytes using a single sample ..." and "[m]ultiple electrode sensors may also be used to improve the precision of the resulting readings ...". See col. 48:16-59. Note that claim 7 does not exclude the first pair of electrodes from also being used measure another analyte different from the analyte measured with the third pair of electrodes. Thus, with the first pair of electrodes and the third pair of electrodes at least two different analytes in the sample can be measured.

Addressing claims 8 and 9, Neel discloses indicating an error if the fill time exceeds a predetermined value (Column 15, lines 19-24).

Addressing claims 10 and 11, Neel et al discloses performing a measurement on the fluid if the fill time is less than a predetermined value (Column 15, lines 26-32).

Addressing claim 12, Neel discloses a method of performing a measurement on a biological fluid in a test strip (abstract) comprising

providing a biological fluid test strip (10) including

a capillary fill chamber (66) extending a length along the test strip from an intake opening (68) to a terminus (70)(Figures 1-3),

a first pair of electrodes (22,24) in operative communication with the chamber (Figure 2),

and

a second pair of electrodes (28,30) in operative communication with the chamber (Figure 2);

dosing the test strip with a biological fluid effective to cause the biological fluid to flow from the intake opening toward the terminus (col. 14:43-51);

applying a first test signal to at least one of the first pair of electrodes (col. 14:48-55);

measuring a first response to the first test signal (col. 14:48-55);

maintaining the first pair of electrodes in an inoperative state after the measuring the first response (col. 14:55-57);

applying a second test signal to at least one of the second pair of electrodes (col. 14:67 – col. 15:03);

measuring a second response to the second test signal (col. 14:67 – col. 15:03).

Neel does not mention the steps of applying a measurement test signal to at least one of the third pair of electrodes after the measuring the second response; measuring a third response to the third test signal; and determining a concentration of an analyte in the biological fluid using the third response.

Feldman discloses an electrochemical biosensor for performing a measurement on a biological fluid. The biosensor comprises multiple working electrodes (42, 44, 46), along with counter electrodes, to form electrode pairs that are in operative communication with a sample chamber (26) on a base material (48) (col. 49:7-12). It would have been obvious to provide at least one additional pair of electrodes, to form a third electrode pair and use it for measuring an analyte concentration, as taught by Feldman in the invention of Neel as modified by Beaty because as taught by Feldman, "... multiple electrode sensors may be used to test a variety of analytes using a single sample ..." and "[m]ultiple electrode sensors may also be used to improve the precision

of the resulting readings ...". See col. 48:16-59. Note that claim 7 does not exclude the first pair of electrodes from also being used measure another analyte different from the analyte measured with the third pair of electrodes. Thus, with the first pair of electrodes and the third pair of electrodes at least two different analytes in the sample can be measured.

Addressing claim 13, for the additional limitation of this claim see in Neel col. 14:35-60, step 348 in Figure 17.

Addressing claim 14, for the additional limitation of this claim see in Neel col. 14:63 – col. 15:11.

Addressing claim 15, for the additional limitations of this claim see in Neel col. 14:27 – col. 15:11 and steps 348-358 in flowchart in Figure 17.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. US 6,743,635 B2 ("Neel") in view of Feldman et al. US 6,592,745 B1 ("Feldman") as applied to claims 7-15 above, and further in view of Beaty et al. US 6,645,368 B1 ("Beaty").

The second test signal applied by Neel as modified by Feldman appears to be just a DC test signal (col. 14:67 – col. 15:03).

Beaty discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip for determining the concentration of a medically significant component of a biological fluid. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel as modified by Feldman as the second test signal because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit, glucose (or other analyte) concentration, temperature, bilirubin concentration, uric acid concentration, and oxygen concentration. See 06:20-42.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 7 recites the limitation "first electrodes" in line 12. There is insufficient antecedent basis for this limitation in the claim.

b) Claim 7 recites the limitation "second electrodes" in line 13. There is insufficient antecedent basis for this limitation in the claim.

c) Claim 7 recites the limitation "third electrodes" in line 17. There is insufficient antecedent basis for this limitation in the claim.

11. Note that dependent claims will have the deficiencies of base and intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Nogueroła
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AU 1795
October 26, 2007